IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

DENISE MCGRATH, Plaintiff, v. BAYER HEALTHCARE PHARMACEUTICALS INC.; BAYER CORPORATION; BAYER HEALTHCARE LLC; BRACCO DIAGNOSTICS, INC.; and MCKESSON CORPORATION, Defendants.	Civ. No. 18-CV-02134-RJD-VMS

PLAINTIFF'S SECOND AMENDED COMPLAINT FOR DAMAGES

Comes now Plaintiff Denise McGrath ("Plaintiff") and alleges as follows:

PARTIES AND BACKGROUND

1. Gadolinium is a highly toxic heavy metal and rare earth element. It does not occur naturally in the human body. The only known route for gadolinium to enter the human body is by injection of a gadolinium-based contrast agent.

2. Plaintiff Denise McGrath is a resident of Brooklyn, New York. Ms. McGrath was injected with linear gadolinium-based contrast agents ("GBCAs") prior to receiving several MRIs in New York. Contrary to the defendant's promotion of GBCAs as being benign contrast agents that harmlessly exit the body shortly after administration in patients with normal kidney function, Ms. McGrath continues to have retained gadolinium in her body, years after being administered the GBCAs.

3. On or around February 24, 2015 and June 15, 2015, Denise McGrath received injections of the linear GBCA Multihance in New York. On or around July 22, 2015, Denise McGrath received an injection of the linear GBCA Magnevist in New York.

4. On September 1, 2015, Denise McGrath received urine test results indicating that the heavy metal gadolinium from the GBCAs remained within her body. On November 9, 2015, Denise McGrath received urine test results confirming her body has retained gadolinium from

the GBCAs she was given.

5. Plaintiff's primary injuries alleged herein are caused by gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin). The gadolinium, a toxic heavy metal, caused fibrosis in organs, bone, and skin, and crossed the blood-brain barrier and deposited in the neuronal nuclei of her brain. Denise McGrath suffers from joint pain, skin and muscle pain, muscle weakness, brain fog, and other injuries caused by the gadolinium that is retained in her body.

6. GBCAs induce cell death and have toxic effects on the mitochondrial function of differentiated human neurons.[1] The magnitude of the measured toxicity broadly increases as the kinetic stability of the contrast agent decreases, and the lower stability agents (such as those given to Plaintiff) induce toxicity at concentrations that fall within the range detected in some autopsy patients. The magnitude of the toxicity increases with concentration.

7. "Gadolinium-based contrast agent-induced adverse effects are entirely man-made diseases. Contemporary medicine cannot revoke its responsibility for complications that occur from the intravenous administration of non-physiologic rare earth metals. Translational scientists are obliged not to be indifferent to patients with gadolinium retention or systemic fibrosis. Medical and environmental research cannot divest itself of the responsibility for understanding how retained gadolinium elicits pathologic effects. Risk is the product of consequence and probability. The consequence of an incurable, chronically painful, and debilitating disorder eclipses the probability of acquiring gadolinium- based contrast agent-induced toxicity with regularity in our clinics and hospitals. We demonstrate that gadolinium-based contrast agents vandalize subcellular organelles and subvert normal mitochondrial function in the kidney in a manner akin to common conditions, such as obesity. These discoveries will help break the vicious cycle in which gadolinium-based contrast agent exposure in patients with normal kidney function or in obese patients lend to the susceptibility to gadolinium-mediated renal

[1] Bower DV, et al., Gadolinium-Based MRI Contrast agents Induce Mitochondrial Toxicity and Cell Death in Human Neurons, and Toxicity Increases With Reduced Kinetic Stability of the Agent. *Invest. Radiol*. 2019; 00: 00-00)

pathologies."[2]

8. There is widespread evidence that GBCAs are biologically-active and can trigger profound systemic fibrosis.[3],[4],[5], [6], [7], [8]

9. The specific markers for GBCA-induced systemic fibrosis have been found in a patient with normal renal function who underwent 61 contrast-enhanced examinations (a variety of gadolinium-based contrast agents, including MultiHance, Magnevist, Omniscan, and ProHance) between 19 and 30 years of age. A skin biopsy demonstrated the presence of gadolinium, with absorbance peaks matching those of Magnevist and MultiHance. Joint contractures (a major clinical criterion for NSF) was present in his neck and all four extremities to the point where the patient became non-ambulatory.[9]

10. Plaintiff was never warned about the risks of gadolinium retention because she had normal renal function and the GBCA manufacturers chose to only provide warnings to patients with reduced renal function.

11. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, and Bayer Healthcare LLC (collectively referred to as the "Bayer Defendants') manufacture, market, and sell Magnevist, a gadolinium-based contrast agent that was injected into Plaintiff's body.

12. Defendant Bayer Healthcare Pharmaceuticals Inc. is a Delaware corporation with

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[2] Do C, et al. Gadolinium-based contrast agents: Stimulators of myeloid-induced renal fibrosis and major metabolic disruptors. *Elsevier Toxicology and Pharmacology*. 2019.
[3] Do, C., et al., Type of MRI contrast, tissue gadolinium, and fibrosis. *Am J Physiol Renal Physiol*, 2014. 307(7): p. F844-55.
[4] Wagner, B., et al., Nephrogenic systemic fibrosis: Evidence for bone marrow derived fibrocytes in skin, liver, and heart lesions using a 5/6 nephrectomy rodent model. *Am J Pathol*, 2012. 181(6): p. 1941-52.
[5] Drel, V.R., et al., Centrality of bone marrow in the severity of gadolinium-based contrast-induced systemic fibrosis. *FASEB J*, 2016. 30(9): p. 3026-38.
[6] Corot, C., et al., Structure-activity relationship of macrocyclic and linear gadolinium chelates: investigation of transmetallation effect on the zinc dependent metallopeptidase angiotensin-converting enzyme. *J Magn Reason Imaging*, 1998. 8(3): p. 695-702.
[7] Bhagavathula, N., et al., Fibroblast response to gadolinium: role for platelet derived growth factor receptor. *Invest Radiol*, 2010. 45(12): p. 769-77.
[8] Sieber, M.A., et al., A preclinical study to investigate the development of nephrogenic systemic fibrosis: a possible role for gadolinium-based contrast media. *Invest Radiol*, 2008. 43(1): p. 65-75.
[9] Roberts, D.R., et al., High Levels of Gadolinium Deposition in the Skin of a Patient With Normal Renal Function. *Invest Radiol*, 2016. 51(5): p. 280-9.

its principal place of business in New Jersey. Defendant Bayer Healthcare Pharmaceuticals Inc. is the United States pharmaceuticals unit of Bayer Healthcare LLC. Bayer Healthcare Pharmaceuticals Inc. is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Magnevist into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

13. Defendant Bayer Corporation is an Indiana corporation with its headquarters located in Pennsylvania. Defendant Bayer Corporation is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Magnevist into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

14. Defendant Bayer HealthCare LLC is a Delaware LLC with its headquarters located in New Jersey. Bayer HealthCare LLC is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Magnevist into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities. This Court has personal jurisdiction over Bayer HealthCare LLC under the doctrine of specific jurisdiction because the subject incident arises out of and relates to Bayer HealthCare LLC's forum-related activities – namely the marketing, advertising, and sale of Magnevist to Denise McGrath and her doctors. No member or owner of Bayer HealthCare LLC is domiciled in New York. The officers of Bayer HealthCare LLC reside in Pennsylvania, New Jersey, Kansas, and California. Bayer

HealthCare LLC members and owners are Delaware corporations or limited liability companies. For any member of Bayer HealthCare LLC that is also a limited liability company, all of their underlying members and owners are Delaware or European corporations or limited partnerships.

15. Defendant Bracco Diagnostics Inc. manufactures, tests, markets, advertises, and sells the linear GBCA named MultiHance.

16. Defendant Bracco Diagnostics, Inc. is a Delaware corporation with its principal place of business in New Jersey. Bracco Diagnostics, Inc. is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing MultiHance into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

17. Defendant McKesson Corporation ("McKesson") distributes Magnevist, MultiHance and other gadolinium-based contrast agents in New York. Plaintiff alleges that McKesson distributed the Magnevist and MultiHance that was injected into Plaintiff.

18. Defendant McKesson Corporation is a Delaware corporation with its principal place of business in California. McKesson Corporation is duly authorized to conduct business in the state of New York and does significant business in the Eastern District of New York. McKesson is engaged in the business of storing, distributing, selling, marketing, and/or introducing Magnevist and MultiHance into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

19. As used herein, "Defendants" includes Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, and Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation.

20. Defendants are authorized to do business in the Eastern District of New York and derive substantial income from doing business in this state.

21. Upon information and belief, Defendants purposefully availed themselves of the privilege of conducting activities with the Eastern District of New York, thus invoking the benefits and protections of its laws.

22. Upon information and belief, Defendants did act together to design, sell, advertise, manufacture, promote and/or distribute Magnevist and MultiHance, with full knowledge of its dangerous and defective nature.

JURISDICTION AND VENUE

23. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity jurisdiction). The amount in controversy exceeds $75,000 exclusive of interest and costs. There is complete diversity of citizenship between Plaintiff and Defendants. Plaintiff is a resident and citizen of and is domiciled in the State of New York. As set forth more fully above, all Defendants are entities organized in states other than the State of New York, all Defendants have their principal place of business in a state other than the State of New York, and none of the Defendants is a citizen or resident of the State of New York.

24. This Court has personal jurisdiction over Defendants, each of which is licensed to conduct and/or is systematically and continuously conducting business in this state, including, but not limited to, the marketing, researching, testing, advertising, selling, and distributing of drugs, including GBCA's of the type received by Ms. McGrath, to the residents in this state.

25. The Bayer Defendants, at all relevant times, have and had significant contacts with the State of New York. The Bayer Defendants are all registered to do business in the State of New York with the New York Secretary of State. The Bayer Defendants operated at facility in Tarrytown, New York. The Bayer Defendants conducted clinical trials and other research regarding Magnevist in the State of New York. The Bayer Defendants sold the Magnevist that was administered to Plaintiff in the State of New York. Plaintiff received the injection of Defendant's Magnevist in the State of New York.

26. Defendant Bracco Diagnostics, Inc., at all relevant times, has and had significant contacts with the State of New York, including conducting clinical trials and other research regarding MultiHance in the State of New York. Defendant Bracco Diagnostics sold the MultiHance that was administered to Plaintiff in the State of New York. Plaintiff received the injection of Defendant's MultiHance in the State of New York.

27. Defendant McKesson Corporation at all relevant times, has and had significant contacts with the State of New York. Defendant McKesson Corporation is registered to do business in the State of New York with the New York Secretary of State. Defendant McKesson Corporation distributed and sold the Magnevist and MultiHance that was administered to Plaintiff in the State of New York. Plaintiff received the injections of the Magnevist and MultiHance in the State of New York.

28. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a), because Plaintiff lives in, and suffered her injuries in, this District. Defendants marketed, advertised, and distributed the dangerous product in this District, Defendants do substantial business in this state and within this District, and Defendants developed, manufactured, promoted, marketed, tested, researched, distributed, warranted, and sold the referenced GBCAs in interstate commerce.

FACTS COMMON TO ALL CAUSES OF ACTION

29. Plaintiff Denise McGrath underwent MRIs during which she was injected with the linear GBCAs Magnevist and MultiHance. Plaintiff Denise McGrath had normal kidney function at the time she was injected with these GBCAs. The gadolinium that Ms. McGrath was injected with was retained in her body and resulted in fibrosis in her organs, skin, and bones, retained gadolinium in the neuronal nuclei of her brain, and related injuries.

30. The type of gadolinium retention sustained by Plaintiff occurs in patients with normal or near-normal renal function that develop persistent symptoms that arise hours to months after the administration of a linear gadolinium-based contrast agent. Ms. McGrath had no preexisting disease or subsequently developed disease of an alternate known process to account for the symptoms. This is a progressive condition for which there is no known cure.

31. During the years that Defendants manufactured, marketed, distributed, sold, and administered linear gadolinium-based contrast agents, there have been numerous case reports, studies, assessments, papers, peer reviewed literature, and other clinical data that have described and/or demonstrated gadolinium retention in connection with the use of linear gadolinium-based contrast agents

32. Defendants failed to warn Plaintiff and her healthcare providers about the serious health risks associated with linear gadolinium-based contrast agents, and failed to disclose the fact that there were safer alternatives (e.g., macrocyclic agents instead of linear agents).

33. As a direct and proximate result of receiving injections of linear gadolinium-based contrast agents manufactured, distributed, marketed, and/or sold by Defendants, Plaintiff developed gadolinium retention resulting in fibrosis in her organs, skin, and bones, retained gadolinium in her brain, and related injuries.

34. Defendants have repeatedly and consistently failed to advise consumers and their healthcare providers of the causal relationship between linear gadolinium-based contrast agents and gadolinium retention resulting in fibrosis in the organs, skin, and bones, retained gadolinium in the brain, and related injuries. Defendants knew or should have known of the risks posed by linear gadolinium-based contrast agents to individuals with normal or near-normal kidney function.

35. Had Plaintiff and/or her healthcare providers been warned about the risks associated with linear gadolinium-based contrast agents, she would not have been administered linear gadolinium-based contrast agents and would not have been afflicted with gadolinium retention resulting in fibrosis in her organs, skin, and bones, retained gadolinium in her brain, and related injuries.

36. As a direct and proximate result of Plaintiff being administered linear gadolinium-based contrast agents, she has suffered severe physical injury and pain and suffering, including, but not limited to, gadolinium retention resulting in fibrosis in her organs, skin, and bones, retained gadolinium in her brain, and related injuries.

37. As a direct and proximate result of being administered linear gadolinium-based contrast agents, Plaintiff suffered and continues to suffer significant mental anguish and emotional distress and will continue to suffer significant mental anguish and emotional distress in the future.

38. As a direct and proximate result of being administered linear gadolinium-based contrast agents, Plaintiff has also incurred medical expenses and other economic damages and will continue to incur such expenses in the future.

39. The nature of Plaintiff's injuries and damages, and their relationship to linear gadolinium-based contrast agents, were not discovered, and through reasonable care and due diligence could not have been discovered, by Plaintiff, until a time less than two years before the filing of this complaint. Prior to filing this complaint, Ms. McGrath took a urine test that conclusively demonstrated the continued presence of toxic levels of gadolinium in her body.

40. The manufacturers of the linear GBCAs have known since the 1980s that their drugs could cause retention of toxic gadolinium. But their claims to the public and healthcare providers have been misleading and false.

41. In 1984 – prior to FDA approval – the inventors of linear gadolinium-based contrast agents claimed that their product, Gd-DTPA, did not cross the blood-brain barrier, and that the bonds between the toxic gadolinium and its protective coating did not break inside the body. Additionally, they claimed that there would be no toxic gadolinium residue left behind to cause illness.[10]

42. There are two basic types of contrast agents differentiated by their chemical structure – linear agents and macrocyclic agents. The main difference is that the linear agents do not fully surround the gadolinium ion, whereas the macrocyclic agents form a more complete ring around the gadolinium ion which creates a stronger bond. The linear agents include: Magnevist (manufactured by Bayer), Omniscan (manufactured by GE), OptiMark (manufactured

[10] Brasch RC. Inherent contrast in magnetic resonance imaging and the potential for contrast enhancement – the 1984 Henry Garland lecture. *West J Med.* 1985 Jun; 142:847-853.

by Guerbet/ Mallinckrodt/ Liebel-Flarsheim), and MultiHance (manufactured by Bracco).

43. Magnevist, a linear agent, was the first gadolinium-based contrast agent to reach the market after receiving FDA approval in 1988.

44. In 1988 it was recognized in a paper that gadolinium was breaking free from the bonds in the linear-based contrast agents and this was in part due to the competition for its protective layer (chelate) by other essential metals in the body such as zinc, copper, and iron.[11] Furthermore, emerging science showed that the bond between toxic gadolinium and its chelate or cage (Gd-DTPA) became very weak and separates easily in low pH conditions such as those found in many compartments of the human body including extracellular fluid spaces.

45. Stability differences among gadolinium contrast agents have long been recognized in laboratory (in vitro), and deposition of toxic gadolinium in tissues has been described in animal models since at least 1984. The first major study that showed deposition in humans appeared in 1998 regarding patients with renal failure and later in 2004 in patients with normal renal function.[12]

46. Laboratory (in vitro) studies assessing the stability of each gadolinium-based contrast agent in human blood were performed and demonstrated that, over time, greater percentages of gadolinium were released from linear agents as compared to the macrocyclic agents.[13]

47. The lack of stability seen within the linear agents was dismissed as an issue by the defendants claiming that the GBCA's were excreted out of the body according to the drug's claimed half-life, before the chelate could release the toxic gadolinium. However, it was later noted that some conditions could cause prolonged retention of the contrast agents, thus allowing more toxic gadolinium to be released in the bodies of patients. In addition, a delayed elimination

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[11] Huckle JE, Altun E, Jay M, et al. Gadolinium deposition in humans: when did we learn that gadolinium was deposited in vivo? *Invest. Radiol*. 2016; 51:236-240.

[12] *Id.*

[13] Tweedle MF, Eaton SM, Eckelman WC, et al. Comparative chemical structure and pharmacokinetics of MRI contrast agents. *Invest. Radiol*. 1988; 23 (suppl 1): S236-S239; *see also* Frenzel T, Lengsfeld P, Schimer H, et al. Stability of gadolinium-based magnetic resonance imaging contrast agents in serum at 37 degrees C. *Invest. Radiol*. 2008; 43:817-828.

phase of the gadolinium-based contrast agents would later be discovered.

48. Peer-reviewed articles on the deposition of gadolinium in animals with normal renal function, some illustrating deleterious consequences, have been published as early as 1984.[14]

49. Three months after the FDA approval of GE's Omniscan (a linear contrast agent) in 1993 the preclinical safety assessment and pharmacokinetic data were published describing its pharmacokinetics in rats, rabbits, and cynomolgus monkeys. These studies noted that while toxic gadolinium was no longer detectable in the blood 7-days after administration, quantifiable concentrations of gadolinium were persistent in both the renal cortex and areas around bone cartilage.[15]

50. The first report of toxic gadolinium retention in humans may have been presented in September 1989, a little over 1 year after the approval of Magnevist. Authors *Tien et al.* reported that intracerebral masses "remained enhanced on MRI images obtained 8 days after injection of gadolinium DTPA dimeglumine (Magnevist)."[16] Subsequent chemical analysis revealed that a high concentration of gadolinium remained in the tissue.

51. Defendants knew that their linear GBCAs did not have very stable bonds and could come apart easily causing significant toxicity in humans. Defendants have known about the risks that linear gadolinium-based contrast agents pose to people with normal kidney function for years. Pharmacokinetic studies in 1991 indicated that gadolinium retention was occurring in people with normal renal function.[17]

52. In 2004, gadolinium was shown to be deposited in the resected femoral heads (bones) of people who had undergone gadolinium MRI studies.[18] Since then, studies have

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[14] Weinman HJ, Brasch RC, Press WR, et al. Characteristics of gadolinium-DTPA complex: a potential NMR contrast agent. *AJR Am J Roentgenol*. 1984; 142: 619-624.
[15] Harpur ES, Worah D, Hals PA, et al. Preclinical safety assessment and pharmaco-kinetics of gadodiamide injection, a new magnetic resonance imaging contrast agent. *Invest Radiol.* 1993; 28 (suppl 1): S28-S43.
[16] Tien RD, Brasch RC, Jackson DE, et al. Cerebral Erdheim-Chester disease: persistent enhancement with Gd-DTPA on MR images. *Radiology*. 1989; 172:791-792.
[17] Schumann-Giampieri G, Krestin G. Pharmacokinetics of Gd-DTPA in patients with chronic renal failure. *Invest Radiol.,* 1991; 26:975-979.
[18] Gibby WA, Gibby KA, Gibby WA. Comparison of Gd DTPA-BMA (Omniscan) versus Gd HP-DO3 (ProHance)

continued to indicate that gadolinium remains within people's bodies long after the suggested half-life.

53. Despite this well-documented evidence of gadolinium retention, Defendants have continuously failed to warn consumers and their healthcare providers on the label of their products, or anywhere that a patient or physician could be informed.

54. Dermatologists, nephrologists, and other scientists connected the administration of linear gadolinium-based contrast agents to a rapidly progressive, debilitating and often fatal condition called gadolinium-induced "Nephrogenic" Systemic Fibrosis (NSF), prompting the Food and Drug Administration (FDA) to issue a black box warning regarding the release of toxic gadolinium from the linear contrast agents, and its long-term retention in the bodies of animals and humans (for patients with abnormal kidney function) on all gadolinium-based contrast agents in 2007.

55. Because of the black box warning and the medical community's awareness of the clear causal connection between GBCAs and NSF in renally impaired patients, the incidence of NSF has all but disappeared, as healthcare practitioners have universally changed MRI prescription habits.

56. It is now settled in the medical community that GBCAs are a cause of NSF. Authoritative and reliable medical literature has reported that the relative risk for development of the disease in renally impaired patients exposed to GBCAs might be as high as 41 (a 4,000% increased risk over baseline) compared to baseline.[19]

57. The kidneys play a central role in the body's clearance of GBCAs, but the name "nephrogenic" systemic fibrosis is misleading, as there is in fact no evidence that this systemic fibrotic condition is in any was *caused* by the kidneys.

58. Instead, the kidneys are simply a catalyst, insofar as impaired renal function

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retention in human bone tissue by inductively coupled plasma atomic emission spectroscopy. *Invest Radiol.,* 2004; 39:138-142.

[19] Wagner B., et al. Pathophysiology of gadolinium-associated systemic fibrosis. *Am. J. Physiol. Renal Physiol*., 311(1): p. F1-11 (2016).

results in the body's prolonged exposure to a GBCA dose from an imaging event.

59. Defendants corrected their label to include contraindications for use in people with kidney disease and acute kidney injury.

60. There were over 500 NSF cases reported and estimated to be well over a thousand non-reported.

61. The vast majority of the medical community was not aware, until recently, of any disease that was associated with gadolinium other than NSF, which was defined as only occurring in patients with renal failure.

62. Indeed, by 2017, FDA and industry were forced to acknowledge that gadolinium retention is not a problem only in patients with renal impairment, but instead, that the evidence is now unequivocal that GBCA exposure results in gadolinium being retained in the bodies – tissue and organs, including skin, bones, liver, and brain – of patients who do not suffer from clinically diagnosed renal impairment.

63. As manufacturers and sellers of Mutlihance and Magnevist, the onus is/was on Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation to ensure the safety of their products. After it was discovered the GBCAs were the cause of NSF in patients with clinically diagnosed renal impairment, Defendants could have and should have researched GBCA safety and the possibility/effects of retention in patients not clinically diagnosed with renal impairment. Defendants could have and should have used this newly acquired information and evidence to sound the alarm that non-renally impaired recipients of their products Magnevist and Multihance were at risk for gadolinium retention and toxicity.

64. The Supreme Court in *Wyeth v. Levine* held that "As the FDA explained in its notice of the final rule, " 'newly acquired information' " is not limited to new data, but also encompasses "new analyses of previously submitted data." *Wyeth v. Levine*, 555 U.S. at 569. As such, Defendants could have always re-analyzed the safety information they had on Magnevist and Multihance. Based on this new health and safety information, at any time post-approval,

Defendants could have sought a label change, including doing it without first obtaining FDA approval under a "Changes Being Effected (CBE)" label change. Even though Defendants knew of these serious health reports, they nonetheless failed to timely and adequately warn its customers, including Plaintiff and her healthcare providers, about the serious health risks of gadolinium retention.

65. In May 2013, a study was initiated to further investigate the safety of six different commercially used Gadolinium-containing contrast agents. The study was requested by the European Medicines Agency to further investigate whether Gadolinium in human bone and skin are retained for a long time after administration of Gadolinium-containing contrast agents. The study was developed to evaluate Gadolinium retention in patients with renal function ranging from stable to severely impaired renal function.[20]

66. In October 2014, Bracco Diagnostics, Inc. started a study entitled "A Prospective Multicenter Cohort Study Evaluating the Long Term Retention of Gadolinium in Human Bone and Skin After the Retrospective Administration of MultiHance or ProHance in Comparison With a Control Group Receiving No Exposure to Gadolinium."[21]

67. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation engaged in a deliberate and conscious effort to disregard the obvious logical conclusion that because gadolinium toxicity is not caused by impaired renal function, it is thus is a danger to people without diagnosed renal insufficiency. These Defendants intentionally and consciously chose not to engage in immediate and thorough research on risks of gadolinium retention and toxicity in patients with normal renal function because they did not want to undermine their products thereby reducing profits.

68. Gadolinium toxicity is, therefore, an underreported and underdiagnosed condition. Over the past several years (since the link between gadolinium-based contrast agents and NSF was acknowledged) patients with normal renal function have been forming advocacy groups and

[20] https://clinicaltrials.gov/ct2/show/NCT01853163
[21] https://clinicaltrials.gov/ct2/show/NCT03108378

coming forward to create awareness for their condition. Symptomatic patients often have documentation of high levels of gadolinium in their blood and urine long after their exposure to gadolinium-based contrast agents. Many patients also have tissue biopsies of various parts of their body that show additional evidence of retained gadolinium years after their exposure.

69. Some patients sent several strongly worded letters with scientifically-supported research data to the FDA, warning about the occurrence of gadolinium toxicity in those with normal renal function following injections of gadolinium-based contrast agents. Correspondence was confirmed as early as 2012.

70. In 2013, while examining non-contrast enhanced MRI images, Japanese researchers found evidence of retained gadolinium in the brains of patients with normal renal function that had previously received one or more injections of gadolinium-based contrast agents up to several years prior. They found that the brain had hyperintense signals in critical areas of the brain.[22]

71. These findings were confirmed by scientists at the Mayo Clinic in 2014 when autopsy studies were performed on 13 deceased individuals, all of whom had normal or near normal renal function and who had received six or more injections of gadolinium-based contrast agents in the years prior. Up to 56 mcg of gadolinium per gram of desecrated tissue were found within the brains of these patients.[23]

72. In July of 2015, in response to the Mayo Clinic study's findings, the FDA issued a new public safety alert stating that the FDA is evaluating the risk of brain deposits from repeated use of gadolinium-based contrast agents used in MRIs.

73. In September 2017, the FDA's medical advisory committee voted 13 to 1 in favor of adding a warning on labels that gadolinium can be retained in some organs, including the brain, even in patients with healthy kidneys.

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[22] Kanda T, Ishii K, Kawaguchi H, et al. High signal intensity in the dentate nucleus and globus pallidus on unenhanced T1-weighted MR images: relationship with increasing cumulative dose of a gadolinium-based contrast material. *Radiology*. 2014; 270: 834-841.

[23] McDonald RJ, McDonald JS, Kallmes DF, et al. Intracranial gadolinium deposition after contrast-enhanced MR imaging. *Radiology*. 2015; 275:772-782.

74. On May 21, 2018, the GBCA manufacturers finally issued a joint warning to patients with normal kidney function. This new "Important Drug Warning" issued by Bayer, GE, Bracco, and Guerbet included the following:

a. "Subject: Gadolinium from GBCAs may remain in the body for months to years after injection;"
b. A new class warning, patient counseling, and a medication guide;
c. Warning that gadolinium is retained for months to years in several organs;
d. Warning that the highest concentrations of retained gadolinium are found in bone, followed by organs (brain, skin, kidney, liver, and spleen);
e. Warning that the duration of gadolinium retention is longest in bone and varies by organ;
f. Warning that linear GBCAs cause more retention than macrocyclic GBCAs;
g. Warning about reports of pathological skin changes in patients with normal renal function;
h. Warning that adverse events involving multiple organ systems have been reported in patients with normal kidney function;
i. Warning that certain patients are at higher risk:
    i. patients with multiple lifetime doses;
    ii. pregnant patients;
    iii. pediatric patients;
    iv. patients with inflammatory process;
j. Instructions for health care providers to advise patients that:
    i. Gadolinium is retained for months or years in brain, bone, skin, and other organs in patients with normal renal function;
    ii. Retention is greater following administration of linear GBCAs than following administration of macrocyclic GBCAs.

The Warning deliberately downplays the state of the evidence concerning the health effects of gadolinium retention.

75. Defendants are estopped from asserting a statute of limitations defense because all Defendants fraudulently concealed from Plaintiff the nature of Plaintiff's injuries and the connection between her injuries and the Defendants' tortious conduct.

76. The risk of gadolinium retention and physical injury such as those suffered by Plaintiff was knowable at the time Mutihance and Magnevist were manufactured/sold. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation actually knew or should have known of the need to issue a warning via the Changes Being Effected provision regarding the retention of gadolinium and risk of physical injury it causes. This information was generally available or reasonably obtainable in the industry. In that regard, Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation had information from other sources such as complaints from users, sellers, or distributors of physical injury suffered as a result of gadolinium retention caused by MultiHance and Magnevist.

77. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation could have and should have used a Changes Being Effected supplement to amend their label/instructions with this newly acquired information.

FIRST CAUSE OF ACTION
(Against All Defendants)
STRICT PRODUCT LIABILITY: FAILURE TO PROVIDE ADEQUATE WARNING

78. Plaintiff incorporates by reference and realleges each paragraph set forth above.

79. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation's linear gadolinium-based contrast agents were defective due to inadequate warnings or instruction for use, both prior to marketing and post-marketing.

80. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation knew or should have known that their products created significant risks of serious bodily harm to consumers yet Defendants failed to adequately warn Plaintiff and her healthcare providers of such risks.

81. At all relevant times, Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation were in the business of designing, researching, manufacturing, testing, promoting, marketing, selling, and/or distributing the pharmaceutical drugs Magnevist and Multihance as herein described that were used by Plaintiff, or has acquired entities that did the same.

82. Multihance and Magnevist are and were defective at the time they were administered to Plaintiff because they failed to contain adequate warnings or instructions because they did not contain information that they could be retained in people with normal renal function, nor information that said retention could cause physical injury, such as that suffered by Plaintiff.

83. Multihance and Magnevist are and were less stable than available macrocyclic gadolinium-based contrast agents.

84. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation are therefore liable by virtue of the following acts and/or omissions:

a) Failing to adequately and correctly warn the Plaintiff, the public, and her medical and healthcare providers of the dangers of MultiHance and Magnevist with respect to the risk of gadolinium retention;

b) Failing to disclose their knowledge that gadolinium from MultiHance and Magnevist is retained for months to years in several organs;

c) Failing to disclose their knowledge that higher concentrations of retained gadolinium are found in bone, followed by organs (brain, skin, kidney, liver, and spleen);

d) Failing to disclose their knowledge that gadolinium retention is longest in

bone and varies by organ;

e) Failing to disclose their knowledge that linear GBCAs cause more retention than macrocyclic GBCAs;

f) Failing to disclose their knowledge about adverse event reports involving multiple organ systems in patients with normal renal function;

g) Failing to disclose their knowledge that certain patients are at higher risk of adverse effects from linear GBCAs;

h) Failing to disclose their knowledge of adverse health effects patients who've retained gadolinium develop;

i) Failing to disclose their knowledge that gadolinium has a tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain;

j) Manufacturing, producing, promoting, formulating, creating, and/or designing their linear GBCAs without thoroughly, adequately, and/or sufficiently testing it – including pre-clinical and clinical testing and post-marketing surveillance – for safety and fitness for use and/or dangers and risks;

k) Marketing their linear GBCAs to Plaintiff, Plaintiff's healthcare providers, the public, and the medical and healthcare professions without adequately and correctly warning and/or disclosing the existence, severity, and duration of known or knowable side effects from the retention of gadolinium in the brain, skin, organs, and bones;

l) Marketing their linear GBCAs to Plaintiff, her healthcare providers, the public, and the medical and healthcare professions without providing adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, their linear GBCAs;

m) Marketing their linear GBCAs to Plaintiff, her healthcare providers, the

public, and the medical and healthcare professions without proper warnings and adequate warnings or labeling regarding adverse side effects and health risks associated with the use of their linear GBCAs and the comparative severity and duration of such adverse effects;

n) Advertising and recommending their linear GBCAs without sufficient knowledge of their safety profiles;

o) Advertising and recommending their linear GBCAs without proper or adequate rate of incidence of the prevalence of gadolinium retention and associated side effects;

p) Representing to Plaintiff, Plaintiff's healthcare providers, the public, and the medical and healthcare professions that their linear GBCAs were superior to other commercially available products designed to provide the same MRI scan image contrast, when in fact they were not;

q) Designing, manufacturing, producing, and/or assembling their linear GBCAs in a manner that was dangerous to their users;

r) Concealing information from Plaintiff, Plaintiff's healthcare providers, the public, other medical and healthcare professionals, and the FDA that their linear GBCAs were unsafe, dangerous, and/or nonconforming with FDA regulations;

s) Concealing from and/or misrepresenting information to Plaintiff, Plaintiff's healthcare providers, other medical and healthcare professionals, and the FDA concerning the existence and severity of the risks and dangers of their linear GBCAs, as compared to other commercially available MRI contrast agents;

t) Encouraging the sale of their linear GBCAs either directly or indirectly, orally or in writing, to Plaintiff and Plaintiff's healthcare providers without warning about the need for more comprehensive and regular medical

monitoring than usual to ensure early discovery of potentially serious side effects; and

u) Representing to physicians, including but not limited to Plaintiff's prescribing physicians, that their linear GBCAs were safe and effective as well as without potentially serious side effects as a result of gadolinium retention.

91. Had Plaintiff not taken Multihance and/or Magnevist, Plaintiff would not have suffered injuries and damages as set forth herein. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered physical and emotional damages, mental anguish, and diminished enjoyment of life, and will require lifelong medical treatment, monitoring, and/or medications.

92. Had Plaintiff and her medical providers been adequately warned of the risks associated with their GBCAs, Plaintiff would not have used MultiHance or Magnevist or agreed to being administered with these drugs.

93. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation as the manufacturers and/or sellers of Multihance and Magnevist had a duty to provide adequate warnings and instructions about the dangers Multihance and Magnevist present as a result of the retention of gadolinium in people's bodies.

94. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation failed to provide a warning that a reasonably prudent manufacturer or seller in the same circumstances would have provided to people receiving Multihance and Magnevist.

95. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation failed to provide a warning that a reasonably prudent manufacturer or seller in the same circumstances would have provided to adequately communicate information on the dangers and safe use of Multihance and Magnevist

to physicians, taking into account the characteristics of, and the ordinary knowledge common to, such prescribing physicians regarding the risks of gadolinium retention in peoples' bodies and the related physical injuries.

96. McKesson Corporation, as the sellers of MultiHance and Magnevist had a duty to provide adequate warnings or instructions about the dangers MultiHance and Magnevist present as a result of the retention of gadolinium in people's bodies.

97. McKesson Corporation failed to provide a warning that a reasonably prudent seller in the same circumstances would have provided to people receiving MultiHance and Magnevist.

98. McKesson Corporation failed to provide a warning that a reasonably prudent seller in the same circumstances would have provided to adequately communicate information on the dangers and safe use of MultiHance and Magnevist to physicians, taking into account the characteristics of, and the ordinary knowledge common to, such prescribing physicians regarding the risks of gadolinium retention in peoples' bodies and the related physical injuries.

99. The risk of gadolinium retention and physical injury such as those suffered by Plaintiff was knowable at the time Mutihance and Magnevist were manufactured/sold. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation actually knew or should have known of the need to issue a warning via the Changes Being Effected provision regarding the retention of gadolinium and risk of physical injury it causes. This information was generally available or reasonably obtainable in the industry. In that regard, Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation are experts in their field. Moreover, Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation had information from other sources such as complaints from users, sellers, or distributors of physical injury suffered as a result of gadolinium retention caused by MultiHance and Magnevist.

100. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation also breached their post-

sale duty to warn. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation had knowledge, actual or constructive, which was available at the time of distribution so that an effective and reasonable supplemental warning could have been given.

101. Information about the danger of fibrosis and retention was reasonably available or obtainable at the time of distribution.

102. When Plaintiff was administered Multihance and Magnevist they was not misused or substantially altered in any way that was not reasonably foreseeable.

103. At the time of administration, Multihance and Magnevist were used for their intended purpose, which was to provide contrast to an image obtained via MRI scan.

104. Plaintiff was a direct and reasonably foreseeably user of Multihance and Magnevist.

105. Had Plaintiff and/or her healthcare providers received adequate warning/instructions as alleged above, she would not have been administered Multihance and Magnevist, and would not have suffered injury.

106. Multihance and Magnevist were the proximate cause of Plaintiff's injuries, as alleged herein.

107. The Multihance and Magnevist received by Plaintiff lacked such warnings/instructions as specified above when it left Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation's control.

108. Multihance and Magnevist were defective due to inadequate warnings or instruction for use, both prior to marketing and post-marketing.

109. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation knew or should have known that their products created significant risks of serious bodily harm to consumers, yet they failed to adequately warn consumers and their healthcare providers of such risks.

110. As a result of Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation's failure to provide adequate warnings for their products, Plaintiff was unknowingly injected with dangerous linear GBCAs which the Defendants manufactured, designed, sold, supplied, marketed, or otherwise introduced to Plaintiff.

111. The linear GBCAs injected into Plaintiff are the legal cause of Plaintiff's serious physical injuries, harm, damages, and economic loss. Plaintiff will continue to suffer such harm, damages, and economic loss in the future.

112. The foregoing acts, conduct, and omissions of Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation were vile, base, willful, malicious, wanton, oppressive and fraudulent, and were done with a conscious disregard for the health, safety and rights of Plaintiff and other users of Defendants' products, and for the primary purpose of increasing Defendants' profits.

113. Multihance and Magnevist are designed in such a way that, when used as intended, it causes serious, permanent and devastating injuries to patients who receive it. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation acted unreasonably in their design of the product in that they failed to adopt a safer design, such as a macrocyclic design, for their contrast agent even though it was practical, feasible, and an otherwise reasonable alternative design or formulation that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of Multihance and Magnevist.

114. Multihance and Magnevist did not perform as safely as an ordinary patient would expect when used in their intended manner or in a manner reasonably foreseeable.

115. The risks of Multihance and Magnevist outweigh their benefits.

116. There were numerous safer alternatives and macrocyclic agents that in reasonable probability would have prevented or significantly reduced the risk of personal injuries suffered by Denise McGrath without substantially impairing its utility and such safer alternative designs were

economically and technologically feasible at the time the products left control of Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation by the application of existing or reasonably-achievable scientific knowledge.

117. Any warnings actually provided Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation did not sufficiently and/or accurately reflect the symptoms, type, scope, severity, and/or duration of these side effects, particularly the risk of retention and fibrosis.

118. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation failed to properly and adequately warn and instruct Plaintiff and her health care providers as to the risks and benefits of Multihance and Magnevist , given the Plaintiff's conditions and need for information.

119. Without adequate warnings of these side effects, Multihance and Magnevist are not reasonably fit, suitable, or safe for its reasonably anticipated purpose.

120. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation intentionally, recklessly, and maliciously misrepresented the safety, risks and benefits of Multihance and Magnevist in order to advance their own financial interests, with wanton and willful disregard for the rights and health of Plaintiff.

121. Further, Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation misrepresented facts as set forth herein concerning the characters or qualities of the Multihance and Magnevist that would be material to her prescribers and purchasers of the product.

122. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation's misrepresentations were made to potential prescribers and/or purchasers and/or users as members of the public at large.

123. As a purchaser and user, Plaintiff and/or her healthcare providers reasonably relied

on the misrepresentations and omissions.

124. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation improperly, negligently, falsely, and deceptively misrepresented or knowingly omitted, suppressed, or concealed facts of such materiality regarding the safety and efficacy of Multihance and Magnevist to and/or from the FDA, that had the FDA known of such facts, Multihance and Magnevist would have never been approved with the warnings and instructions for use that accompanied them and/or were provided to the prescribing physicians and the public, so that Multihance and Magnevist would not have been prescribed to nor used by Plaintiff.

125. Because Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation knowingly withheld and/or misrepresented information required to be submitted under FDA regulations, which information was material and relevant to the harm in question, that these decisions were economically driven manipulation of the post market regulatory process, and that Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation knew or should have known in the post marketing phase that Multihance and Magnevists's label was inadequate based on the label warning updating requirements of the FDA, no statutory presumptions in favor of Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation are warranted.

126. Despite the fact that Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation knew or should have known that Multihance and Magnevist caused unreasonably dangerous side effects, they continued to market, manufacture, distribute, and/or sell Multihance and Magnevist to consumers, including Plaintiff.

127. Plaintiff and Plaintiff's healthcare providers were therefore forced to rely on safety information that did not accurately represent the risks and benefits associated with the use of linear

GBCAs as compared to other products already commercially available to provide the same services.

128. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation failed to comply with federal requirements. Specifically, it is believed that they failed to timely report adverse events; failed to timely conduct investigations and analyses; failed to timely report any and all information concerning Multihance and Magnevists's risks and side effects; failed to timely and fully inform the FDA of unanticipated side effects, increases in the incidence of side effects, or the products' failures necessitating a labeling, manufacturing, or design modification; failed to conduct necessary design validation and sold a misbranded and adulterated product.

129. Had Plaintiff not taken Multihance and Magnevist, Plaintiff would not have suffered injuries and damages as set forth herein. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered physical and emotional damages

130. As a result of Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation's failure to provide adequate warnings for their products, Plaintiff was unknowingly injected with dangerous linear gadolinium-based contrast agents which the Defendants manufactured, designed, sold, supplied, marketed, or otherwise introduced into the stream of commerce.

131. The linear GBCAs injected into Plaintiff are the legal cause of Plaintiff's serious physical injuries, harm, damages, and economic loss. Plaintiff will continue to suffer such harm, damages, and economic loss in the future.

132. The foregoing acts, conduct and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive and fraudulent, and were done with a conscious disregard for the health, safety and rights of Plaintiff and other users of Defendants' products, and for the primary purpose of increasing Defendants' profits. As such, Plaintiff is entitled to exemplary or punitive damages.

SECOND CAUSE OF ACTION
(Against All Defendants)

NEGLIGENCE

85. Plaintiff incorporates by reference and realleges each paragraph set forth above.

86. Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, labeling, marketing, sale and distribution of their linear gadolinium-based contrast agents. In particular, they had a duty to assure that their products did not pose an unreasonable risk of bodily harm and adverse events.

87. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, marketing, or distribution of their linear gadolinium-based contrast agents in that they knew or should have known that these products could cause significant bodily harm or death, and were not safe for use by consumers.

88. Defendants failed to exercise ordinary care in the labeling of their linear gadolinium-based contrast agents and failed to issue to consumers and their health care providers adequate warnings concerning the risks of serious bodily injury due to the use of linear GBCAs.

89. Despite the fact that Defendants knew or should have known that their linear gadolinium-based contrast agents posed a serious risk of bodily harm to consumers, Defendants unreasonably continued to manufacture and market linear gadolinium-based contrast agents and failed to exercise reasonable care with respect to post-sale warnings and instructions for safe use.

90. At all relevant times, it was foreseeable to Defendants that consumers like Plaintiff would suffer injury as a result of Defendant's failure to exercise ordinary care as described above.

91. Defendants are liable for their absence and inadequacy of a warning of latent dangers resulting from the foreseeable uses of Magnevist and MultiHance of which they knew or should have known, and for breaching their post-sale duty to warn.

92. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, and Bayer Healthcare LLC, Bracco Diagnostics, Inc., and McKesson Corporation (hereinafter "Defendants"), failed to warn Plaintiff and her healthcare providers of the risks of gadolinium retention (following administration of their linear GBCAs Magnevist and MultiHance) in

patients with normal kidney function, and the risks of gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), and resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain.

93. As a result of Defendants' breaches of the above-mentioned duties, Plaintiff was injured.

94. Plaintiff did not learn of the potential cause of her injuries until April 2016.

95. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered physical injuries, emotional injuries, harm, non-economic and economic damages, and economic loss, and will continue to suffer such harm, damages, and economic loss in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

a) Non-economic damages including pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;

b) Economic damages including past and future medical expenses, past and future loss of income, loss of earning capacity, and other economic damages in an amount to be determined at trial of this action;

c) Punitive damages as allowed by law and in an amount to be determined at the time of trial of this action;

d) Pre-judgment and post-judgment interest;

e) Attorneys' fees, expenses, and costs; and

f) Such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

In addition to the above, Plaintiff hereby demands a trial by jury for all causes of action and issues that can be tried by a jury.

Dated: March 27, 2019

CUTTER LAW, P.C.

By: _____
Todd A. Walburg

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CERTIFICATE OF SERVICE

I, Todd A. Walburg, an attorney, hereby certify that on March 27, 2019, a copy of this SECOND AMENDED COMPLAINT was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's CM/ECF.

/s/ Todd A. Walburg
Todd A. Walburg